

§ 40.52

licensed to receive the source or by-product material.

[45 FR 65532, Oct. 3, 1980]

§ 40.52 Certain items containing source material; requirements for license to apply or initially transfer.

An application for a specific license to apply source material to, incorporate source material into, manufacture, process, or produce the products specified in § 40.13(c) or to initially transfer for sale or distribution any products containing source material for use under § 40.13(c) or equivalent provisions of an Agreement State will be approved if:

(a) The applicant satisfies the general requirements specified in § 40.32. However, the requirements of § 40.32(b) and (c) do not apply to an application for a license to transfer products manufactured, processed, or produced in accordance with a license issued by an Agreement State or to the import of finished products or parts.

(b) The applicant submits sufficient information regarding the product pertinent to the evaluation of the potential radiation exposures, including:

(1) Chemical and physical form and maximum quantity of source material in each product;

(2) Details of construction and design of each product, if applicable. For coated lenses, this must include a description of manufacturing methods that will ensure that the coatings are unlikely to be removed under the conditions expected to be encountered during handling and use;

(3) For products with applicable quantity or concentration limits, quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;

(4) The proposed method of labeling or marking each unit, and/or its container with the identification of the manufacturer or initial transferor of the product and the source material in the product; and

(5) The means of providing radiation safety precautions and instructions relating to handling, use, and storage of products to be used under § 40.13(c)(1)(i) and (c)(1)(iii).

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(c) Each product will contain no more than the quantity or the concentration of source material specified for that product in § 40.13(c).

[78 FR 32340, May 29, 2013]

§ 40.53 Conditions for licenses issued for initial transfer of certain items containing source material: Quality control, labeling, and records and reports.

(a) Each person licensed under § 40.52 shall ensure that the quantities or concentrations of source material do not exceed any applicable limit in § 40.13(c).

(b) Each person licensed under § 40.52 shall ensure that each product is labeled as provided in the specific exemption under § 40.13(c) and as required by their license. Those distributing products to be used under § 40.13(c)(1)(i) and (iii) or equivalent regulations of an Agreement State shall provide radiation safety precautions and instructions relating to handling, use, and storage of these products as specified in the license.

(c)(1) Each person licensed under § 40.52 shall file a report with the Director, Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 40.5(a), including in the address: ATTN: Document Control Desk/Exempt Distribution.

(2) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee and indicate that the products are transferred for use under § 40.13(c), giving the specific paragraph designation, or equivalent regulations of an Agreement State.

(3) The report must include the following information on products transferred to other persons for use under § 40.13(c) or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s), if applicable;

(ii) For each type of source material in each type of product and each model number, if applicable, the total quantity of the source material; and

(iii) The number of units of each type of product transferred during the reporting period by model number, if applicable.